MARYLAND MEDICAID PHARMACY PROGRAM

Prior Authorization Criteria for Incivek® (telaprevir)

1. Confirmed diagnosis of chronic hepatitis C, genotype 1, and compensated liver disease including cirrhosis (Child-Pug B score must be <6) in adult recipients who are treatment naive or who have been previously treated with interferon-based drug regimen, including null and partial responders and relapsers. Recipient has not previously failed therapy with a Hep C Protease Inhibitor. Deny for decompensated liver disease. A high proportion of previous null responders, particularly those with cirrhosis, did not achieve sustained virologic response and had telaprevir resistance-associated substitutions emerge on treatment with Incivek.

2. Case-by-case determination of coverage for recipients with HIV, liver or solid organ transplant. Approval may be considered if recipient is co-managed by an experienced HIV or transplant provider. Recipients with substance or alcohol use must be abstinent before considered for treatment.

3. Recipient must be over 18 y/o.

4. Recipient is not a pregnant female or a male with a pregnant female partner, a ribavirin contraindication.

5. Prescriber or Consultant must be an infectious d/s or GI specialist or hematologist.

6. Drug must be initiated with combination of peg-interferon alpha and ribavirin. Deny if used as monotherapy.

7. Contraindications: Co-administration with drugs which are highly dependent on CYP3A for clearance and for which elevated plasma concentrations are associated with life-threatening events or that strongly induce CYP3A which may lead to loss of efficacy of Incivek. Refer to the Contraindications and Drug-Drug Interactions Section of the FDA drug monograph. All contraindications to peginterferon alfa, ribavirin also apply.

8. If Recipient meets the clinical criteria, a Service Prior-Authorization (PA) will be entered in the system for the entire 3-month telaprevir length of therapy or for a total of 504 tablets. However, claims must be submitted each month for a quantity of 168 tablets, 28 days supply. The FDA-recommended dosage for telaprevir is 2 tablets of 375mg (or 750mg) orally every 8 hours with food (not low fat). Telaprevir comes in a 28-day package of 168 tablets.

9. The Service PA may be terminated by the Program staff at any particular time if the therapy must be discontinued based on the manufacturer's Response-Guided Therapy (RGT) guidelines or treatment futility rules (see attached Hep C Protease Inhibitor Response-Guided-Therapy Guidelines for teleprevir and boceprevir).

10. Submission of the completed Hep C Protease Inhibitors PA Form along with test results of the baseline and follow-up HCV-RNA viral levels by the treating physician are required. A copy of the medical history summary and the doctor's progress notes must initially accompany the request for drug prior-authorization. Drug tolerance, adherence and response to guided therapy are conditions for payment for continuation of therapy in accordance with the drug manufacturer-established treatment timelines. The Program Clinical Pharmacist will be monitoring patient

compliance and response to Hep C therapy via communication with the medical office and collection of clinical data and lab test results which include the HCV-RNA viral levels obtained from the medical office.

11. To avoid the emergence of resistance, all treatment including PEG INF and RBV, should be discontinued if any of the following occur:

- HCV RNA is > or =1000 IU/mL at WK 4 or 12 for telaprevir;
- HCV RNA detectable at wk 24 or at any other time point thereafter.
- HCV RNA rebounds (>=1 log 10 increase from the nadir HCV RNA) at any time while on treatment.

12. Telaprevir should not be dose-reduced. If boceprevir or telaprevir is discontinued, it should not be restarted. If ribavirin is stopped for >=7 days or discontinued secondary to adverse events, then telaprevir should also be discontinued to avoid development of resistance.

Prior Authorization Criteria for Victrelis® (Boceprevir)

1. Confirmed diagnosis of chronic hepatitis C, genotype 1, and compensated liver disease, including cirrhosis (Child-Pug B score must be <6) in adult recipients who are previously untreated or who have failed previous interferon and ribavirin therapy. Deny for decompensated cirrhosis or liver disease. Recipient has not previously failed therapy with a Hep C Protease Inhibitor. Victrelis in combination with peginterferon alfa and ribavirin has not been studied in null responders (<2-log10 HCV-RNA decline by TW12) during prior therapy with peginterferon alfa and ribavirin. The clinical studies included subjects who were poorly interferon responsive.
2. Case-by-case determination of coverage for recipients with HIV, liver or solid organ transplant. Approval may be considered if recipient is co-managed by an experienced HIV or transplant provider. Recipients with substance or alcohol use must be abstinent before considered for treatment.
3. Recipient must be over 18 y/o.
4. Recipient is not a pregnant female or a male with a pregnant female partner (a ribavirin contraindication).
5. Prescriber or Consultant must be an infectious d/s or GI specialist or hematologist.
6. Recipient must have been on a treatment regimen of ribavirin and pegylated interferon for 4 weeks before Victrelis is added. Deny if Victrelis is prescribed as monotherapy.
7. Contraindications: Co-administration with drugs which are highly dependent on CYP3A4/5 for clearance and for which elevated plasma concentrations are associated with life-threatening events or with potent CYP3A4/5 inducers which may significantly reduce Victrelis plasma concentrations and efficacy. Refer to the Contraindications and Drug-Drug Interactions Section of the FDA drug monograph. All contraindications to peginterferon and ribavirin also apply.

8. Pharmacy may bill for 336 capsules (4x 200mg capsules) for a 28-day supply per claim. The FDA-recommended dosage for boceprevir is 800mg every 8 hours with food plus peginterferon alpha plus ribavirin. Boceprevir comes in a 28-day package of 336 capsules.

9. If the recipient meets the clinical criteria for the Hep C triple drug therapy, a Service Prior-Authorization (PA) will be entered in the system for the entire length of treatment with boceprevir to allow for uninterrupted therapy. The duration of therapy varies from 28 weeks to 44 weeks, depending on patient characteristics (whether the patient is a historical null responder or previously untreated, poor interferon responders), and on response to treatment (HCV-RNA levels). However, claims are limited to a 28-day supply or 168 tablets. A service prior-authorization will be entered in the system for the approved length of therapy to avoid therapy interruption. However, in order to minimize drug wastage, refills should not be dispensed automatically (on auto-fill system) by the specialty pharmacy unless the dispensing pharmacist could verify with the prescriber that the recipient has tolerated the Hep C multi-drug regimen and has had no problem with adherence. The Service PA may be terminated by Program staff at any particular time if the therapy must be discontinued based on the manufacturer's Response-Guided Therapy (RGT) guidelines or treatment futility rules (see attached Hep C Protease Inhibitor Response-Guided-Therapy Guidelines for teleprevir and boceprevir).

10. Submission of the completed Hepatitis C Protease Inhibitor PA Form by the prescriber is required along with test results for baseline HCV-RNA viral level prior to the start of the triple drug regimen and whenever such test is due (at TW8, TW12, TW24, and monthly thereafter while Recipient is on boceprevir. A copy of the medical history summary and doctors' progress notes must accompany the initial request for drug prior-authorization. Approval of continuation of therapy is based on the viral levels per manufacturer's Response-Guided Therapy (RGT) guidelines. Drug tolerance, adherence and response to therapy are conditions for continuation of the triple drug regimen. The Program Clinical Pharmacist will be monitoring patient compliance and response to Hep C therapy via communication with the medical office and collection of clinical data and lab test results which include the HCV-RNA viral levels obtained from the medical office.

11. To avoid the emergence of resistance, all treatment including PEG INF and RBV, should be discontinued if any of the following occur:

- HCV RNA > or = 100 IU/ml at WK 12 for boceprevir
- HCV RNA detectable at wk 24 or at any other timepoint thereafter.
- HCV RNA rebounds (>=1 log 10 increase from the nadir HCV RNA) at any time while on treatment. Note: The dosage of peginterferon or ribavirin may be reduced, but no dosage adjustment must be made to boceprevir which should not be dose-reduced. If boceprevir is discontinued, it should not be restarted. If ribavirin is stopped for >=7 days or discontinued secondary to adverse events, then boceprevir should also be discontinued to avoid development of resistance.
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